

REMARKS

Claims 1, 3-6, and 8-35 were pending at the time of the Office action. Claims 33 and 34 have been withdrawn from consideration. Claims 1, 3-6, 8-20, 27, and 29 stand rejected under 35 U.S.C. § 102. Claims 1, 3-6, 8-32, and 35 stand rejected under 35 U.S.C. § 103. Applicant addresses these rejections as follows.

Claim Amendments

Claim 1 has been amended to correct minor typographical errors.

Applicant reserves the right to pursue any cancelled subject matter in this or in a continuing application. No new matter has been added.

Rejections under 35 U.S.C. § 102

Claims 1, 3-6, 8-20, 27 and 29 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Li et al. (*P Soc Exp Biol Med.* 220: 218-224, 1999; herein “Li”), as evidenced by Dou et al. (U.S. Patent Application Publication No. 2002/0151582; herein “Dou”). The Examiner states (page 3) that Li “teach[es] administering tea orally and topically to human[s] with oral precancerous mucosa lesions...” and cites Dou as evidentiary support that the green tea extracts of Li contain polyphenolic compounds (e.g., EGCG).

Applicant respectfully traverses this rejection on the basis that Li fails to teach a method for treating a pre-cancerous lesion of the skin of a patient by administering a pharmaceutically effective amount of a polyphenol to the patient. Li, in contrast to the claimed methods, describes treating oral pre-cancerous mucosa lesions by administering a capsulated mixture of dried tea extract and topically applying a glycerin-based mixture of the extract to the oral mucosa lesions. Consequently, and contrary to the Examiner’s assertion, Li does not describe each and every element of claim 1. This basis for the anticipation rejection should be withdrawn.

Claims 1, 3-6, and 8-20 also stand rejected under 35 U.S.C. § 102(b) as being anticipated by Jia et al. (*Cancer Epidem Biomar.* 11: 1663-1667, 2002; herein “Jia”). The Examiner states (page 3) that Jia “teach[es] the effects of tea polyphenols and tea pigments on rat liver precancerous lesion[s], and the results suggest that tea polyphenols and tea pigments are effective in preventing the precancerous liver lesions in rats...”

Applicant respectfully disagrees with this rejection, noting that Jia describes the effects of tea polyphenols on pre-cancerous lesions found on rat livers. The treatment method described by Jia does not include treating pre-cancerous skin lesions. Thus, Jia fails to describe each and every element of the claimed invention and, therefore, cannot anticipate claim 1 or its dependent claims. This basis for the 35 U.S.C. § 102 rejection should also be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1, 3-6, 8-27, and 29 stand further rejected under 35 U.S.C. § 103(a) as being unpatentable over Li, as evidenced by Dou. According to the Examiner (page 5), Li “do[es] not teach the amount of the polyphenols in the composition... [but] it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the inventions of Li et al since they provide scientific data for human oral precancerous mucosa lesions...”

This rejection is respectfully traversed because Li, as evidenced by Dou, fails to teach or suggest all the claim limitations required to support a *prima facie* case of obviousness. As described above, Li describes the administration of a tea extract for the treatment of oral mucosa lesions, but fails to describe methods for treating pre-cancerous skin lesions, as currently claimed. Because the skin and oral mucosa differ significantly in their cellular composition, organization, location, and function, it would not have been obvious to apply the teachings of Li to arrive at the present invention. Furthermore, Li says nothing about the amount of the polyphenols present in the compositions

administered, as noted by the Examiner. Thus, Li, alone or as evidenced by Dou, fails to teach or suggest all the elements of claims 1, 3-6, 8-27, and 29, and Applicant respectfully requests that this rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

Claims 1, 3-6, and 8-26 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Jia. The Examiner states (page 6) that Jia “do[es] not teach the amount of the polyphenols in the composition... [but] it would have been *prima facie* obvious... to use the inventions of Jia et al since it provides scientific data for treating rat liver precancerous lesions...”

Applicant respectfully disagrees. Jia describes the effects of tea polyphenols on pre-cancerous lesions found on rat livers, but fails to teach or suggest that this same composition could be used to treat pre-cancerous lesions of the skin, as indicated above in the response to the § 102(b) rejection. It would not have been obvious to one skilled in the art to apply the teachings of Jia to the present invention, considering that the skin and liver are different organs with different functions and cellular compositions. In addition, Jia is silent about the amount of the polyphenols present in the compositions administered, as noted by the Examiner. Thus, Jia fails to teach or suggest all of the elements of claims 1, 3-6, and 8-26 and, as such, this basis for rejection under 35 U.S.C. § 103 should be withdrawn.

Claims 1, 3-6, 8-32, and 35 stand further rejected under 35 U.S.C. § 103(a) as being unpatentable over Li in view of Brash et al. (U.S. Patent Application Publication No. 2002/0198161; herein “Brash”) and further in view of Voet (U.S. Patent No. 6,723,750; herein “Voet”), as evidenced by Dou. The Examiner cites Li for reasons described above. Turning to Brash and Voet, the Examiner states (page 8) that “it would have been *prima facie* obvious... to use the carrier isopropyl myristate [in] ointment form from Brash et al, and the treatment of curettage from Voet in the current invention...”

This rejection is respectfully traversed. As discussed above, Li does not describe methods for treating pre-cancerous skin lesions by administering a tea extract, as

presently claimed. Brash and Voet fail to cure the deficiencies of Li. Brash teaches that skin precancers may be treated topically with a sulfuric compound present in a carrier (e.g., isopropyl myristate), while Voet teaches curettage for treating cancerous or pre-cancerous skin lesions. Thus, Li, alone or in combination with Brash and Voet, fails to teach or suggest a method for treating pre-cancerous skin lesions by administering a tea extract, and reconsideration and withdrawal of this rejection is respectfully requested.

Finally, claims 1, 3-6, 8-28, 30-32, and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Jia in view of Brash and further in view of Voet, as evidenced by Dou. The Examiner cites Jia, Brash, and Dou for reasons discussed above. As indicated above in the response to the § 102(b) rejection, Jia does not describe methods for treating pre-cancerous skin lesions by administering a tea extract, and Brash and Voet fail to cure this deficiency. Accordingly, this final basis of rejection under 35 U.S.C. § 103(a) may also be withdrawn.

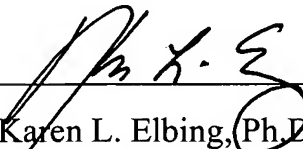
CONCLUSION

Applicant submits that the claims are now in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for one month, to and including April 17, 2008, and a check in payment of the required extension fee.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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